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CONFIRMATION NO.

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EXAMINER

ZEMAN, ROBERT A

ART UNIT

PAPER NUMBER

1645

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/932,503	Applicant(s) MORCOL ET AL.	
	Examiner Robert A. Zeman	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-21 is/are pending in the application.
- 4a) Of the above claim(s) 18-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment and response filed on 11-3-2005 are acknowledged. Claims 1-11 have been canceled. Claims 19-21 have been added.

Newly submitted claims 19-21 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the elected invention is drawn to methods of delivering therapeutic agents utilizing compositions comprising calcium phosphate particles wherein said agents are associated with the core of calcium phosphate particles and wherein said particles are at least partially covered with a layer of casein (Group III of the restriction requirement) whereas claims 19-21 are drawn to the compositions (Group I of the restriction requirement).

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 19-21 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Additionally, claim 18 was withdrawn from consideration since the claimed method utilized a different composition (i.e. particles with cores comprising calcium phosphate and polyethylene glycol). Consequently, claims 12-21 are pending. Claims 18-21 have been withdrawn from consideration. Claims 12-17 are currently under examination.

Claim Rejections Withdrawn

The rejection of claims 12-17 are rejected under 35 U.S.C. 103(a) as being obvious over Bell et al. (U.S. Patent 6,355,271) in view of Corrigan et al. (WO 99/03451)

Art Unit: 1645

is withdrawn. In the Declaration filed on 11-3-2005, Applicant has stated the subject matter disclosed and claimed by U.S. Patent 6,355,271 was owned by the same person or subject to an obligation of assignment to the same person at the time the instantly claimed invention was made as the instant application. Accordingly, Applicant *makes a clear statement of entitlement* to exclude U.S. Patent Nos. 5,731,168-A, 5,807,706-A, and 5,821,333-A as prior art, as provided by 35 USC § 103(c).

New Grounds of Rejection

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 12-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nuwayser (U.S. Patent 5,648,097 – IDS) and Corrigan et al. (WO 99/03451).

Art Unit: 1645

The instant invention is drawn to a method of delivering a therapeutic amount of a therapeutic agent to a patient comprising orally delivery of one or more particles wherein said particles comprise a calcium phosphate core, a therapeutic agent associated with said core and a casein layer that at least partially covers said core.

Nuwayser discloses methods for adsorbing biologically active compounds to calcium phosphate particles wherein the resulting particles serve as controlled release drug delivery vehicles (see abstract, column 5 lines 16-36). Nuwayser further discloses that the biologically active agent or drug can be any drug or biologically active agents that can be released into an aqueous environment including peptide drugs, antibiotics anti-inflammatory agents, antivirals, etc. (see column 6, lines 5-23). Finally, Nuwayser discloses that the disclosed microparticles can be coated with a biodegradable and /or bioerodible compound in order to alter the delivery profile of the active ingredient (see column 4, lines 18-24).

Nuwayser differs from the claimed invention in that he does not explicitly disclose the use of casein as a coating substance, the use of polyethylene glycol as a surface modifying agent or the use of insulin as the biologically active agent.

Corrigan et al. disclose the use casein in pharmaceutical compositions to reduce the irritating effects of the active ingredient (therapeutic compound) [see page 5 lines 10-14] and to provide controlled release pharmaceutical compositions for oral administration (see page 6, lines 4-6). Corrigan et al. further disclose that casein can be used in conjunction with multiple formulation “forms” including granules (i.e. particles) [see page 7, lines 20-32].

Consequently, it would have been obvious for one of skill in the art to use the casein disclosed by Corrigan et al. in conjunction with the calcium phosphate particles disclosed by Nuwayser et al. in order to take advantage of the increased drug delivery associated with the use of casein and to provide controlled release pharmaceutical compositions for oral administration. Moreover, the skilled artisan would have been additionally motivated to combine the teachings of the aforementioned references in hopes of filling the need for alternative insulin delivery methodologies.

One of ordinary skill in the art would have had a reasonable expectation of success since Corrigan et al. disclose that casein can be used with “granular formulations” and Nuwayser discloses that his particles can be coated with a biodegradable and /or bioerodible compound in order to alter the delivery profile of the active ingredient. Consequently, the combination of the cited references renders all the rejected claims obvious.

It should be noted that while Nuwayser does not explicitly disclose the use of insulin as the biologically active agent, its use is deemed to be an obvious variation of the particles disclosed by Nuwayser since he discloses that the biologically active agent or drug can be any drug or biologically active agents that can be released into an aqueous environment. Additionally, while Nuwayser does not explicitly disclose the use of polyethylene glycol as a surface-modifying agent its use is deemed obvious since Nuwayser discloses that the disclosed microparticles can be coated with a biodegradable and /or bioerodible compound in order to alter the degradation profile of the active ingredient (see column 4, lines 18-24).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

Art Unit: 1645

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 12 and 17 are rendered vague and indefinite by the recitation of the phrase “ a layer of casein at least partially covering and forming a protective coating that encapsulates the core”. It is unclear how a partial covering of casein can encapsulate a core when “encapsulation” by definition means to “encase”.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1645

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



ROBERT A. ZEMAN
PATENT EXAMINER

January 26, 2006